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EXAMINER	
FRAZIER, BARBARA S	
ART UNIT	PAPER NUMBER
1611	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/500,756	ARAUJO ET AL.	
	Examiner	Art Unit	
	BARBARA FRAZIER	1611	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 April 2008*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4 and 8-15* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4 and 8-15* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Status of Claims

1. Claims 1, 2, 4, and 8-15 are pending in this application.

2. Cancellation of claims 3 and 5-7 is acknowledged.

3. Claims 1, 2, 4, and 8-15 are examined.

Claim Rejections - 35 USC § 112

4. The rejection of claims 1-15 under 35 U.S.C. 112, second paragraph, as being indefinite, is withdrawn in view of Applicant's arguments that the term "dispersion" is used in reference to the pigments being dispersed in a single oily phase that include a single oily dispersing vehicle and a single emollient vehicle.

Claim Rejections - 35 USC § 102

5. The rejection of claims 1, 5, 7, 8, and 15 under 35 U.S.C. 102(b) as being anticipated by Lukenbach et al (US Patent 5,980,871) is withdrawn in view of Applicant's amendment to claim 1.

Claim Rejections - 35 USC § 103

6. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

7. Claims 1, 2, 4, 8, and 13-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al (US Patent 5,980,871).

The claimed invention is drawn to an oily dispersion of pigments comprising zinc oxide and titanium dioxide added in the form of a powder to a single oily base in the amounts specified in claim 1, and further comprising a single emollient vehicle (see claim 1).

Lukenbach et al. disclose sunscreen compositions comprising an inorganic sunscreen compound, such as a mixture of titanium dioxide and zinc oxide, in an oil component comprising a carrier oil and at least one emollient (see col. 4, lines 28-37). The inorganic sunscreen compound is oil dispersible (col. 6, lines 34-36), and is added to the oil phase (col. 7, lines 30-34). The amount of titanium dioxide present in the composition is from about 2% to about 25% (col. 6, lines 27-30), and 5% zinc oxide is exemplified (Example 96, col. 13, lines 13-15).

Lukenbach et al do not teach a concentration of titanium dioxide from 30% to 35% by weight.

However, it would have been obvious to a person having ordinary skill in the art at the time the invention was made to adjust the amount of titanium dioxide to 30%; thus arriving at the claimed invention. One skilled in the art would have been motivated to do so because Lukenbach et al's teaching of the amount "about 25%" is comparable to Applicant's teaching of the amount of 30%, especially given that the prior art uses the flexible modifier "about". It would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In

re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 2, Lukenbach et al teach that the titanium dioxide is present in the final composition in an amount from about 2% to about 25% by weight (col. 6, lines 29-30) and zinc oxide is present at 5% (Example 96, col. 13, lines 14-15). Therefore, one having ordinary skill in the art at the time the invention was made would have been motivated to choose a ratio between the pigments of titanium dioxide and zinc oxide of 3:1 as a matter of routine optimization, with a reasonable expectation of success.

Regarding claim 4, Lukenbach et al. teach that titanium dioxide is present in the final composition in an amount of about 2% to about 25% (col. 6, lines 29-30) and that zinc oxide is present in an amount of 5% by weight (col. 13, lines 14-15). This appears to be comparable to the amounts claimed by Applicants, especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of pigment per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235(CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 8, Lukenbach et al. teach that zinc oxide is present at 5% (Example 96, col. 13, lines 13-15). This is encompassed by Applicant's amount of 5 to 10%.

Regarding claim 13, Lukenbach et al. teach that the emollient should be present in the formulation in a ratio to the carrier concentration of from about 1:1 to about 3:1, most preferably about 2:1. This appears to be comparable to the amounts claimed by Applicants, i.e., where the weight percentage **within the oily dispersion** is 45-65%, especially given that the prior art uses the flexible modifier "about". In any case, it would have been obvious to determine workable and/or optimal amounts of emollient per the reasoning of well-established precedent, such as In re Aller, 220 F.2d 454, 456, 105 USPQ 233, 235 (CCPA 1955). (Holding that "[W]here the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation.")

Regarding claim 14, Lukenbach et al teach the concurrent addition of the oil and emollient, followed by addition of titanium dioxide (see col. 7, lines 44-53). Lukenbach et al teach that both titanium dioxide and a mixture of titanium dioxide and zinc oxide are examples of the "inorganic sunscreen agent". Therefore, a person having ordinary skill in the art at the time the invention was made would have been motivated to substitute the mixture of titanium dioxide and zinc oxide for the titanium dioxide in the process outlined in Lukenbach et al, with a reasonable expectation of success.

Regarding claim 15, Lukenbach et al teach that "The compositions of this invention can be incorporated into various cosmetic and personal care products such as hand and body lotions, oils, ointments, lip balm products, facial cosmetics and the like" (col. 7, lines 11-15).

Response to Arguments

8. Applicant's arguments filed 4/17/08 have been fully considered but they are not persuasive.

9. Applicants argue that Lukenbach fails to disclose or suggest a composition having a single oily phase in which the concentration of titanium dioxide ranges from 30% to 35% by weight.

This argument is not persuasive because, as stated above, Lukenbach et al's teaching of the amount "about 25%" is comparable to Applicant's teaching of the amount of 30%, especially given that the prior art uses the flexible modifier "about". It would have been obvious to one skilled in the art to determine workable and/or optimal amounts of pigment through routine experimentation.

10. Applicants also argue that there is no disclosure or suggestion of the benefits that are arrived at with a sun screen composition having the recited ranges of titanium dioxide and zinc oxide. Applicants cite the examples in the instant application which provide compositions having an SPF of 30. Applicants allege that such an SPF is unexpected based on the teachings of the cited references.

This argument is not persuasive. One skilled in the art of sunscreen compositions would reasonably expect that an increase in the concentration of sunscreen agent(s) would result in a concurrent increase in SPF. Indeed, Example 96 of Lukenbach et al teaches that the addition of zinc oxide to a composition already comprising titanium dioxide results a large increase in SPF. Additionally, one skilled in the art would reasonably expect that adjusting the amount of titanium dioxide within the

range of "about 25%" to a higher amount would result in a higher SPF. Furthermore, the examples in the specification having an SPF 30 are not limited to compositions wherein the concentration of titanium dioxide is 30 to 35% by weight, but are merely compositions wherein the **total** concentration of titanium dioxide and zinc oxide is 40% by weight.

Therefore, it is the Examiner's position that the claims are rendered obvious.

11. Claim 9 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US patent 5,980,871, in further view of Choulot et al., US 2004/0191189.

Claim 9 of the claimed invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the particle size of the TiO2 and ZnO pigments used ranges from 15 to 100 nanometers.

Lukenbach et al. teach that titanium dioxide should be used having a primary particle size from of less than about 300 nm in diameter (col. 6, lines 27-29).

Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4).

Lukenbach et al. differ from the claimed invention in claim 9 because the reference is silent with respect to whether or not the mixture of titanium dioxide and zinc oxide is in particulate form (i.e., from 15 to 100 nanometers).

However, since Choulot et al. teach that it is known to use a mixture of titanium dioxide and zinc oxide with a mean particle size being between 1 and 100 nanometers in a sunscreen composition (page 1, paragraph 4), and since both compositions are sunscreen compositions, a person having ordinary skill in the art at the time the invention was made would have been motivated to use a mixture of titanium dioxide and zinc oxide with the size of Choulot et al. in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 2, 4, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claim 9 stands rejected for reasons stated above.

12. Claims 10 and 11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US Patent 5,980,871, in further view of Kaplan, US Patent 5,989,529.

Claims 10 and 11 of the claimed invention are drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further

comprises a single emollient vehicle, and wherein the dispersing vehicle is selected from the group consisting of polyethyleneglycol and silicone esters, particularly dipolyhydroxy stearate PEG 30.

Lukenbach et al. teach that the carrier oil should be selected from the group of polyether interrupted fatty acid esters (col. 5, lines 65-66).

Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of "an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegancy." (col. 1, lines 40-46).

Lukenbach et al. differ from the claimed invention in claims 10 and 11 because they do not specifically teach that the oil is polyethyleneglycol esters or dipolyhydroxy stearate PEG 30.

However, since Kaplan teaches that PEG 30 dipolyhydroxystearate may be advantageously used to permit the formulation of "an improved oil-in-water sunscreen formulation having improved stability, low viscosity and cosmetic elegancy", and since both compositions are drawn to sunscreen formulations, a person having ordinary skill in the art at the time the invention was made would have been motivated to choose dipolyhydroxy stearate PEG 30 as the oil in the sunscreen composition of Lukenbach et al., with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 2, 4, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claims 10 and 11 stand rejected for reasons stated above.

13. Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Lukenbach et al., US Patent 5,980,871, in further view of Liu et al., US Patent 5,916,544.

The instant invention is drawn to an oily dispersion of pigments for protection against UV radiation, characterized by comprising, in a single oily base, zinc oxide and titanium dioxide added in the form of a powder, wherein the two pigments are dispersed in a single oily dispersing vehicle and the dispersion further comprises a single emollient vehicle, and wherein the emollient is selected from the group consisting of isocetyl stearoyl stearate, glycerol tri-2-ethyl hexanoate and propoxylated stearylic alcohol.

Lukenbach et al. teach that the emollient may be "a conventional emollient known to those of ordinary skill in the art as useful in sunscreen products, such as…synthetic emollients such as fatty acid esters and the like" (see col. 6, lines 14-19).

Liu et al. teach that Ceraphyl 791 (isocetyl stearoyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide (for example, see Examples 18 and 19, col. 6, lines 63-64 and col. 8, lines 20-21).

Lukenbach et al. differ from the claimed invention in claim 12 because they do not specifically teach that the emollient is isocetyl stearoyl stearate, glycerol tri-2-ethyl hexanoate, or propoxylated stearylic alcohol.

However, since Liu et al. teach that Ceraphyl 791 (isocetyl stearoyl stearate) is known to be used as an emollient in sunscreen compositions with titanium dioxide and zinc oxide, and since both compositions are sunscreen compositions, a person having

ordinary skill in the art at the time the invention was made would have been motivated to choose isocetyl stearoyl stearate as the fatty acid ester emollient in the composition of Lukenbach, with a reasonable expectation of success.

Response to Arguments

Applicants have not argued the merits of the instant rejection separately from the rejection of claims 1, 2, 4, and 13-15 over Lukenbach et al (US Patent 5,980,871). Accordingly, claim 12 stands rejected for reasons stated above.

Claim Objections

14. Claim 8, as amended, is now dependent on claim 1. Original claim 8 was dependent on claim 7 (now canceled). However, Applicants have labeled the status of amended claim 8 as "Original". It is suggested Applicants correct the status of the claim.

15. Claims 14 and 15 are objected to because they are dependent on canceled claims. Claims 14 and 15, as amended, are dependent on claims 1, 2, 4-7, and 9-13; however, claims 5-7 are canceled.

Conclusion

16. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to BARBARA FRAZIER whose telephone number is (571)270-3496. The examiner can normally be reached on Monday-Thursday 9am-4pm EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571)272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

BSF

/MP WOODWARD/
Supervisory Patent Examiner, Art Unit 1615